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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/407,327	09/28/1999	GEORGE H. LOWELL	406462000102	2613

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	22

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/407,327	LOWELL, GEORGE H.	
	Examin r	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 May 2002* .

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *19* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed on 5-1-2002 is acknowledged. Claim 4 has been amended. Claims 1-4 and 6-16 are pending and currently under examination.

Priority

The amendment to the specification, the request for a Corrected filing receipt and the substitute oath and declaration is also acknowledged. Based on said submissions, Applicant's claim for domestic priority under 35 U.S.C. 120 is deemed perfected.

Claim Rejections Withdrawn

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "derived" is withdrawn in light of the amendment thereto.

The rejection claims 1-4 and 6-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to the recitation of the term "glycolipid" in claims 1 and 6 is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-4 and 16-16 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide and methods of achieving immunity using said vaccines/compositions, does not reasonably provide enablement for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier, nor does it enable methods of achieving immunity using said vaccines/compositions is maintained for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant argues:

1. The specification does not define a "glycolipid" as "a ganglioside or a variety of protein or peptides with hydrophobic anchors" and hence do not include general proteins or peptides within its definition.

2. The reference by Livingston et al. (Vaccine Vol. 11 No. 12, pages 1199-1204, 1993) demonstrates that Applicant has shown the effectiveness of a glycolipid/proteosomes vaccine.

Applicant's arguments have been fully considered and deemed non-persuasive. Based on the definition of "glycolipid" disclosed in the specification, said claims are drawn to compositions/vaccines that comprise a myriad of molecules in addition to gangliosides. The rejected claims are drawn to the compositions/vaccines comprising an effective amount of a

hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier and the prophylactic use of said compositions/vaccines. To be a prophylactic composition, said composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed compositions/vaccines provide any sort of protective immunity in any model system that can be extrapolated to humans or other mammals. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one **glycolipid** and a pharmaceutically acceptable carrier, nor does it enable methods of achieving immunity using said vaccines/compositions.

With regard to the disclosure by Livingston et al., said reference only illustrates the efficacy of a single species of glycolipid (GD3) to induce an immune response against a tumor antigen and as such is not commensurate in scope with the instant claims.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the term "an effective amount". It is unclear is meant by said term "An effective amount" to do to what? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 recites the limitation "lipopolysaccharide" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 is rendered vague and indefinite by the use of the phrase "is from Shigella". It is unclear to what Applicant is referring. Is Applicant referring to a species of *Shigella* or something else? If the former is true, it is suggested the term "is isolated from a species of Shigella" and that dependent claims be amended to reflect said change.

Claim 3 is rendered vague and indefinite by reciting improper Markush language. The ultimate member of the group must be preceded by the term "and". As written, it is impossible to determine the members of the Markush group.

Claim 7 is rendered vague and indefinite by the use of the phrase "providing enhanced immunogenicity". It is unclear how the administration of a "composition" to a subject increases its immunogenicity since immunogenicity is an inherent property of said composition.

Claim 7 and 8 is rendered vague and indefinite by the use of the phrases "impart enhanced immunity" and "impart immunity". It is unclear how the administration of a

Additionally, it is unclear what is meant by the term "enhanced immunity". How does it differ from normal immunity?

Claims 8-16 are rendered vague and indefinite by the use of the phrase "achieving immunity". How is immunity "achieved"? It is suggested that the rejected claims be amended to recite "A method of inducing immunity".

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 6-9 and 16 are rejected under 35 U.S.C. 102(a) as being anticipated by Livingston et al. (Vaccine Vol. 11, No.12, pages 1199-1204, 1993 – IDS-5).

The rejected claims are drawn to the compositions/vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes and at least one non-detoxified antigenic lipopolysaccharide or a **glycolipid** and a pharmaceutically acceptable carrier and the prophylactic use of said compositions/vaccines.

Livingston et al. disclose immunogenic compositions and vaccines comprising an effective amount of a hydrophobic complex consisting essentially of proteosomes (Neisserial outer membrane proteins) and at least one **glycolipid** (GD3) and a pharmaceutically acceptable

carrier and the use of said compositions as vaccines against tumor cells (see abstract and page 1200). Hence, Livingston et al. anticipates all the limitations of the rejected claims.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
January 29, 2003